

ATTACHMENT C
NOTES ON DEPENDENT AND LIMITED PRESCRIBING AUTHORITY BY STATE

AK - Physician Assistants: PAs may prescribe Schedules III-V controlled substances.

Nurses: Advanced registered nurse practitioners (ARNPs) have independent prescribing authority. The Board of Nurses may limit the types of drugs that they can prescribe in accordance with their education and experience.

AZ - Physician Assistants: PAs may prescribe Schedules II-III in a limited 48-hour supply, and Schedules IV-V in a 34-day supply. All prescriptions must contain the name of the supervising physician.

Nurses: Nurse practitioners (NPs) have full prescriptive and dispensing authority upon application and fulfillment of criteria established by the Board of Nursing. NPs may prescribe Schedule II and III drugs (limited to a 48-hour supply per patient) and Schedule IV and V (a one-month supply with no refills per patient). Other drugs may be refilled five times or up to one year.

CA - Nurses: NPs who have satisfactorily completed at least six months of MD-supervised experience in furnishing drugs or devices, who have satisfactorily completed a course in pharmacology and who have been issued a furnishing number by the Board of Nursing may furnish certain drugs or devices incidental to the provision of family planning services.

CO - Physician Assistants: Physicians may delegate limited prescribing authority to certified PAs. PAs may issue prescriptions for non-controlled substances only.

Nurses: NPs may write prescriptions for select drugs pursuant to an established protocol.

CT - Nurses: Nurse practitioners, clinical specialists, nurse midwives and nurse anesthetists may apply for prescriptive practice privileges. ARNPs must apply for licensure in order to prescribe. Dispensing privileges are also granted to ARNPs functioning in public clinics.

DC - Physician Assistants: PAs may sign prescriptions for non-controlled substances on Rx pads that contain the name of the supervising physician and PA.

Nurses: DC provides dependent prescriptive authority for NPs, nurse midwives and nurse anesthetists for Class II-V drugs according to existing federal laws.

FL - Physician Assistants: Legislation passed in 1992 grants PAs dependent authority to prescribe drugs according to a formulary. Although the legislation has been passed, the mechanisms for implementing the legislation will not be fully in place until early fall.

Nurses: NPs have dependent prescriptive privileges for non-controlled substances.

GA - Nurses: Although nurses have no prescribing authority, a 1989 law states that through a protocol a physician may delegate to a nurse in advanced practice the authority to order controlled substances and dangerous drugs.

ID - Physician Assistants: PAs may write prescriptions as agents of their supervising physicians by applying to the board for prescription-writing authority. The board-approved formulary is limited to 24 categories of legend drugs (antibiotics, non-narcotic analgesics, contraceptives, topical and local anesthetics, etc.).

Nurses: Prescribing is allowable for approved NPs based upon a formulary in the rules; NPs may not prescribe controlled substances.

IA - Physician Assistants: Physicians may delegate the function of prescribing drugs, controlled substances, and medical devices to a licensed PA. PAs may prescribe Schedules II-V controlled substances, except Schedule II stimulants and other depressants. PAs may order Schedule II stimulants and depressants with the prior approval and direction of a physician, and may request, receive and supply sample drugs and medical devices.

Nurses: Nurses may write prescriptions for non-controlled substances under an established protocol.

KS - Physician Assistants: PAs may issue prescription orders orally by telephone for Schedule II controlled substances in an emergency. The supervising physician must provide a written prescription within 72 hours. PAs may orally by telephone transmit prescription orders for Schedules III, IV and V controlled substances, as well as non-controlled substances, which may also be prescribed in writing.

Nurses: NPs may prescribe under jointly adopted protocols between the nurse and physician.

ME - Physician Assistants: Physicians may authorize PAs to prescribe or dispense controlled substances. Authorized PAs may issue prescriptions for categories of drugs on the board-approved formulary, which excludes Schedule II controlled substances. All parenterals except insulin are excluded unless prescribed for administration within a hospital, clinic, physician's office or nursing home. The amount of scheduled drugs that may be prescribed may be no more than 100 dose units or a 90-day supply, whichever is less.

Nurses: Prescriptive authority is approved by the Board of Medicine. Limits in prescribing formulary by exclusion (i.e., narcotics).

MD - Nurses: NPs prescribe medications as agreed upon in writing with physicians.

MA - Physician Assistants: PAs may write prescriptions for legend drugs and controlled substances (Schedules II-V). Prescriptions and medication orders must be issued in accordance with guidelines developed by each PA and supervising physician.

MI - Physician Assistants: Physicians may delegate to PAs the prescription of drugs other than controlled substances. The supervising physician's name must be indicated in connection with each individual prescription.

Nurses: Physicians may delegate the prescribing of drugs to RNs, excluding controlled substances.

MN - Physician Assistants: Physicians may delegate to PAs the authority to prescribe and administer legend drugs and medical devices that are appropriate to the practice. This delegation must be approved by the board. Physician and PA must have an internal protocol that lists the drugs and medical devices the PA may prescribe or administer.

Nurses: NPs have prescriptive authority when delegated to do so under a written agreement with a physician. Nurse midwives also have authority to prescribe.

MS - Nurses: NPs have statutory prescriptive authority granted by the Board of Nursing. This authority is based on the accepted protocol, which lists the treatments and medications the NP expects to prescribe in his or her practice. NPs are not allowed to prescribe controlled substances.

MO - Physician Assistants: The regulations do not impose restrictions on the types of drugs that PAs can prescribe. This is left to the discretion of the supervising physician.

MT - Physician Assistants: PAs may prescribe, dispense and administer drugs to the extent authorized by the rules of the medical board and/or the physician's utilization plan. Authority granted to the PA may include Schedule III, IV and V controlled substances, and Schedule II with a 48-hour limit. The medical board does not permit PAs to prescribe thrombolytics.

NE - Physician Assistants: PAs can only prescribe medications as an agent of a supervising physician. The PA may prescribe medications in the name of the supervising physician if the authority has been assigned by the physician (Schedule II controlled substances used for pain control are limited to a 72-hour supply). Prescription label must bear the name of both the PA and the supervising provision.

Nurses: ARNPs have dependent authority based on a practice agreement with their supervising physician.

NV - Physician Assistants: PAs may prescribe poisons, dangerous drugs or devices, but not controlled substances. PAs must be registered with the Board of Pharmacy.

Nurses: ARNPs may prescribe if certified by the Board of Nursing.

NH - Physician Assistants: Prescriptions transmitted by PAs must be based on patient-specific orders from the supervising physician or on written protocols. All Rx for controlled substances must contain the supervising physician's DEA number with the PA's state license number as a three-digit suffix.

NM - Physician Assistants: PAs may prescribe, administer and distribute dangerous drugs other than controlled substances provided it is done under physician supervision and within medical board-approved guidelines and formulary. The formulary lists 70 types of drugs PAs may prescribe.

Nurses: NPs have prescriptive privileges with their own signature in accordance to written protocols with physician supervision.

NY - Physician Assistants: Physicians may assign prescribing authority to registered PAs. PAs may not prescribe controlled substances.

NC - Physician Assistants: PAs are authorized by law to write prescriptions under conditions specified by the state board of medical examiners. PAs may prescribe drugs from a medical board-approved formulary that excludes controlled substances and parenteral preparations except insulin, immunizations, serum, epinephrine and benadryl. A prescription may not indicate a refill except birth control pills and may be for no more than 100 dosage units or a one-month supply.

Nurses: ARNPs may prescribe non-controlled substances under the supervision of a physician.

ND - Physician Assistants: PAs may prescribe controlled substances, except Schedule II, as agents of their supervising physicians.

Nurses: The Board of Nursing is responsible for delegating prescribing authorities. Once approved by the Board, nurses may prescribe drugs under the supervision of a physician. The types of drugs that a nurse can prescribe are determined by their area of expertise (six practice areas) designated by the Board.

OR - Physician Assistants: Physicians may delegate to PAs the authority to administer and dispense limited emergency medications and to prescribe. The medical board's Physician Assistants Committee is authorized to review applications for prescribing and dispensing privileges and to recommend a formulary that may include all or part of Schedules III through V. To prescribe Schedules II through V controlled substances, PAs must be registered with DEA.

PA - Physician Assistants: Regulations are currently under development that would allow PAs to prescribe and dispense drugs at the direction of licensed physicians. The rules include a formulary that excludes Schedules I and II controlled substances. Until the regulations are promulgated PAs have no prescribing authority.

RI - Physician Assistants: PAs may write prescriptions and medical orders. PAs employed by physicians, HMOs or other health care delivery organizations may prescribe legend medications and Schedule V controlled substances, medical therapies, device and diagnostics according to guidelines established by their employers. Guidelines are updated annually. PAs prescribing controlled substances must register with the state drug control division and with DEA.

Nurses: NPs have prescriptive authority for legend drugs but not for controlled substances.

SC - Physician Assistants: Regulations are currently under development that would grant PAs dependent authority to prescribe Schedule V controlled substances. The regulations would also establish a formulary and appropriate protocols. Until these regulations are developed and implemented PAs have no prescribing authority.

Nurses: Nurses are certified through the Board of Nursing for dependent prescribing authority.

SD - Physician Assistants: PAs can communicate information regarding Schedules III-V drugs to the pharmacy either in writing or by phone. PAs must act as agents of physicians to issue prescriptions for controlled substances; the physician decides on drug, dosage, amount and length of therapy.

Nurses: Certified NPs may prescribe under a practice agreement with the supervising physician. NPs act as the agent of the primary supervising physician in providing and prescribing, except for Schedule II controlled substances.

TN - Nurses: Certified NPs may apply to the Board of Nursing for a "certificate of fitness" with privileges to write and sign prescriptions and/or issue non-controlled legend drugs.

TX - Physician Assistants: Physicians may authorize PAs to administer, provide or carry out a prescription drug order (i.e., complete a prescription pre-signed by the supervising physician) in medically underserved areas.

Nurses: ARNPs have prescriptive authority under standing orders or protocols; prescriptions must be "presigned." To be authorized to prescribe the ARNP must serve certain medically underserved populations.

UT - Physician Assistants: PAs may, in accordance with an approved utilization plan, prescribe Schedule IV and V controlled substances for a period not to exceed seven days.

Nurses: All NPs who practice with a physician can apply for prescriptive privileges in accordance with protocols between the NP and physician. NPs can prescribe controlled substances III-V.

VT - Physician Assistants: PAs may prescribe only drugs selected by the supervising physician from the board-approved drug list. The board's approved drug list contains 25 categories. Some categories, such as heavy metal antagonists, antineoplastics, coagulation agents, cardiovascular drugs and oxytoxics, require additional protocols describing in detail the conditions under which the PA will be prescribing. The physician may delegate the prescribing of controlled substances in any of the categories.

VA - Physician Assistants: Regulations are currently being developed that would give PAs dependent authority to prescribe non-controlled substances. The regulations will include a formulary of specific drugs and devices a PA may prescribe under a written protocol with the supervising physician.

Nurses: ARNPs may prescribe most Schedule VI drugs under the supervision of a licensed physician.

WA - Physician Assistants: PAs may issue written or oral prescriptions when approved by the board and assigned by the supervising physician. Prescriptions for drugs in Schedule II-V may be issued for patients under the care of the sponsoring physician.

WV - Physician Assistants: PAs in all settings may issue prescriptions at the direction of their supervising physician. A state formulary excludes Schedule I and II controlled substances, anticoagulants, antineoplastics, radiopharmaceuticals, general anesthetics, and radiographic contrast materials. Drugs listed under Schedule III are limited to a 72-

hour supply without refill. Medical board rules exclude parenterals, except insulin and epinephrine, from the formulary.

Nurses: ARNPs have limited authority to prescribe, including some controlled substances.

WI - Physician Assistants: Supervising physicians may direct a PA to prepare a prescription order for non-controlled substances if the PA prepares the prescription order only in patient situations specified and described in written protocols; the PA consults directly with the physician, when practicable, prior to preparing a prescription; and the prescription contains the name and address of the physician and PA.

WY - Physician Assistants: PAs may prescribe medications as an agent of the supervising physician, except for Schedule I and II controlled substances. When prescribing controlled substances the supervising physician's DEA number is used.

Nurses: Current legislation states that nurses have prescribing and dispensing capabilities under a "collaborative agreement" with a physician. The Attorney General is currently in the process of determining whether this "collaborative agreement" constitutes independent or dependent prescribing authority. Until the issue is resolved nurses do not have prescriptive authority for controlled substances.

 Cardinal Health

TO: Tom Blaylock/National Specialty Serv. DATE: September 7, 1993
John Dewees/Marmac
Paul Exley/Ohio Valley
Rick Gliot/Chapman
Pat Jensen/Syracuse
Ben Jones/Bailey
Brian Landry/Mississippi
Doug Pace/Florida
John Roth/Solomons
Roy Stromski/Daly
Carol Verrastro/Ellicott
FROM: Steve Reardon *stew*
SUB: DEA Registrations

CC: George Bennett/Dublin
Pete Westermann/Dublin
Linda Zarlengo/Dublin

At a recent meeting with DEA in Washington, D.C., Jim Pacella, DEA's Policy Unit Chief, discussed DEA registration verification issues with NWDA's Regulatory Affairs Committee. The points Mr. Pacella made are summarized as follows:

- Local DEA offices have been instructed not to verify DEA registrations verbally via the telephone. The reason is that certain wholesalers were using this as the sole means of verifying their customers' DEA registration numbers. Despite these instructions, however, I am aware of local offices that continue to verify numbers over the telephone. My recommendation is that if, in emergency situations, your local DEA office will provide this service, then you should continue to use it as long as the verification is documented on a Regulatory Agency Contact Form. This method, however, should not replace your existing Registration Verification Procedure.
- Local DEA offices should not be verbally issuing DEA registration numbers upon inspections of new registrants. DEA's policy is that a person is not registered until the registration certificate is issued. Although DEA Washington denies it, I know that local DEA offices continue this practice. Again, if your local DEA offices operate in this manner, you should take advantage and service your customer as long as you document the verification and request from your customer a copy of the certificate immediately upon receipt.

- A 60-90 day registration renewal grace period exists during which time you can continue to sell to customers who have yet to receive their renewed registration. I would recommend that you obtain a copy of the customer's renewal application and processed check if possible.
- For those accounts who operate on a physician's DEA registration, the physician's name should also appear on the records for that account; i.e., the invoice should show:

ABC Clinic
Dr. John Smith

If you have any questions regarding these issues, please call.



U.S. Department of Justice

(2)

Drug Enforcement Administration

Washington, D.C. 20537

NOV 29 1993

Ms. Diane P. Goyette
Director of Regulatory Affairs
National Wholesale Druggists' Association
1821 Michael Faraday Drive
Suite 400
Reston, Virginia 22090-5348

Dear Ms. Goyette:

This is in response to your correspondence of November 4, 1993, requesting information on any written clarification of security issues prepared by the Drug Enforcement Administration concerning specifications for cages and security containers. The Office of Diversion Control (OD) routinely disseminates security information to its field offices as part of its effort to insure uniform interpretation and application.

Recently, two security notices were prepared and distributed to the field Diversion Investigators. One addressed the new GSA specification revision for Class 5 security containers and the other addressed the cage configuration utilized for the storage of Schedule III-V controlled substances. The following is a synopsis of those two notices:

Class V Security Containers: This notice covered the General Services Administration's (GSA) specification revisions for improved, manipulation-resistant combination locking devices used on GSA Class 5 and 6 security containers and vault doors. This revision was intended to counter surreptitious entry using an auto-dialing device and/or radiological or emanations analysis. As a result, the specifications were changed to read as follows: "20 man-hours against surreptitious entry; 30 man-minutes against covert entry; and 20 man-hours against radiological techniques."

This notice further stated that only one lock, the Mas-Hamilton X-07, meets the new specifications without modifications. It further explained that the security

Ms. Diane P. Goyette

Page Two

standards listed in 21 CFR 1301.72(a)(1)(i) and 1301.72(a)(3)(ii) have not been revised to agree with the new GSA specifications.

- Lastly, the notice re-emphasized the fact that the regulations do not require a registrant to utilize a GSA Class 5 container. Instead, the regulations spell out the minimum security requirements for a security container or vault door used for the storage of Schedule I and II controlled substances. There are several security containers which, when equipped with a Group 1-R three position dial-type combination lock, meet the current Federal requirements.

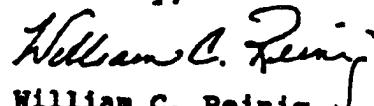
Schedule III-V Cage Specifications: This notice clarified the construction specifications for cages utilized for the storage of Schedule III-V controlled substances. As described in 21 CFR Section 1301.72(b)(4)(ii), a cage's mesh construction cannot have openings greater than 2 1/2" across the square. The confusion existed with the phrase "across the square" which is not a standard size measurement used by cage manufacturers to describe mesh fabric. The industry measurement for mesh size is the minimum distance between the wires forming the parallel sides of the mesh.

Some field offices were interpreting this measurement to be the diagonal distance from corner to corner, while other offices were using the distance between the parallel sides of the mesh configuration. A size comparison of the two options shows a substantial mesh size difference.

Based on this comparison and the intent of this regulation, it was decided that the 2 1/2" measurement has to be interpreted as the greatest point of separation in the mesh configuration. Another way of describing this regulation requirement is that the mesh size cannot exceed 1 3/4" by industry standards.

I trust that the above information adequately addresses your request. If you have any additional questions, please do not hesitate to contact this office.

Sincerely,



William C. Reinig
Security Specialist
Office of Diversion Control

 Cardinal Health

TO: Tom Blaylock
Brendan Connolly
Paul Exley
Ben Jones
David Kozaczka
Brian Landry
George Oughterson
Doug Pace
John Roth
Roy Stromski
Mike Vaughan
Carol Verrastro

DATE: February 14, 1994
FROM: Steve Reardon
SUB: **DEA Security Issues**

CC: George Bennett
Pete Westermann

Attached, for your information and your DEA file, is a letter from Bill Reinig, DEA Diversion Security Specialist, to Diane Goyette, NWDA Director of Regulatory Affairs. The purpose of the letter is to summarize two security notices recently distributed to DEA field offices. One addressed a new GSA Class V specification for vault door construction; the other, controlled substance cage construction.

Evidently, as a result of the change in the GSA Class V vault door specifications, some local DEA offices were requiring vault doors of this new design. Reinig, in the letter, explains that while the GSA description did change, DEA regulations do not automatically require use of a GSA Class V door. Several different designs can meet DEA requirements. The cage construction section is self-explanatory.

If you have any questions, please call.

Attachment



Cardinal Health, Inc.
INTEROFFICE MEMORANDUM

To: Martin Alires/Syracuse
Bill Becker/Florida
Brendan Connolly/Ellicott
Mike Davison/Behrens-Lubbock
John Dewees/Marmac
Paul Exley/Ohio Valley
Jack George/Behrens-Waco
Ben Jones/Chapman
Les Killebrew/Mississippi
Harry Myers/Humiston Keeling
George Oughterson/PRN
John Roth/Solomons
Roy Stromski/Daly
Loren Todd/Bailey

CC: Joe Neary/Whitmire
Pete Westermann/Dublin

From: Steve Reardon *Steve*

Date: July 28, 1994

Re: Order Forms (DEA Form 222)

Attached for your information and your DEA file is a letter issued by DEA to further clarify their position on the proper completion of DEA Form 222 with respect to number of lines completed. The regulatory interpretation is as follows:

- When a purchaser has used five lines on a DEA Form 222 to order controlled substances, and two lines contain entries for the same product and package size, the number of items ordered would be four. If the purchaser erroneously indicated that five items had been ordered, DEA would deem this a minor error which could be corrected.

Please read the letter for the specifics of this interpretation and pass the information on to the appropriate personnel in your division.

If you have any questions, please call.

Attachment

Cardinal Health, Inc.
INTEROFFICE MEMORANDUM

To: Distribution
From: Steve Reardon, Joe Neary
Date: August 12, 1994
Re: Reverse Management Systems (3CI) Waste Disposal Program

Cardinal Health, Inc., has entered into an agreement with Reverse Management Systems (3CI) to dispose of our non-hazardous waste, including controlled substances, legend drugs, OTC items, and aerosols. Reverse Management Systems is registered with the Drug Enforcement Administration in Schedules II, III, IV and V, the Texas Department of Health, and the Texas Department of Public Safety. This registrant status allows them to receive and take possession of controlled substances and legend drugs for the purpose of disposal via incineration.

The pricing schedule is as follows:

1-24,999	pounds	\$.045/lb.
25T-74,999	pounds	\$.043/lb.
75T-99,999	pounds	\$.041/lb.
> 100 T	pounds	\$.039/lb.

The total pounds will be counted over a twelve-month period that will start with our first shipment. The steps to facilitate this process are outlined on the following page.

It is strongly recommended that this service be our sole method of disposal so that we may take advantage of volume discounts and assure compliance with applicable Federal, State, and local regulations. We believe that Reverse Management Systems (3CI) can provide us with a simple, efficient, and economical means to manage pharmaceutical waste. Please contact Joe Neary or me if, for some reason, you do not intend to utilize this service.

If you have any questions, please call.

Attachment



Cardinal Health, Inc.

PREPARING PRODUCT FOR DESTRUCTION

STEP ONE:

To arrange for destruction, contact:

Mr. Dennis Ingles, Operations Manager
Reverse Management Systems
DEA Number RE0196611
201 San Augustine Street
Center, Texas 75935

1-800 RX REVERSE (797-3837), or Fax 1-409-598-9539

STEP TWO:

Reverse Management Systems will provide you with DEA 222 Forms for your Schedule II products.

STEP THREE:

Create a debit memo or zero dollar invoice to Reverse Management Systems. This will serve as documentation of the transfer and create required records (ARCOS, etc.).

STEP FOUR:

When preparing product for shipment:

1. Verify that each return is packed according to the products on the schedule II form.
2. Segregate, and package separately, all other schedules from the legend products.
3. Pack aerosols separately.
4. Note that legend and OTC product do not need to be packaged in any special order.
5. Notify Reverse Management Systems by telephone or fax as to when shipment will be made.
6. Attach an A.O.D. tag to the top of the box for all orders to be shipped UPS. All other shipments must have some other proof of delivery receipt.
7. Include a copy of the debit memo or invoice with the shipment.

STEP FIVE:

Upon completion of the products' incineration, you will receive the following receipts:

- a) A copy of the completed DEA Form 41.
- b) A detailed burn report, itemizing each box with third party verification.
- c) An invoice detailing the amount based on per pound price.
- d) Documentation showing the accurate weight and the actual destruction, by incineration date, verified by third party municipality.



**CARDINAL HEALTH, INC.
MEMORANDUM**

TO: Division Managers / Directors of Operation

FROM: Steve Reardon *Steve*

DATE: June 28, 1995

SUBJECT: Regulatory Reminder

CC: Michael Proulx
Joe Neary
Art Hammerschmidt
Carol Verrastro

When providing back-up delivery service to another division's customers there are licensing and record keeping issues that must be addressed in order to assure compliance with applicable regulatory requirements. These requirements are as follows:

LICENSING:

Transactions between divisions (except in Georgia and Ohio) qualify for an intra-company exemption, and state licensure is not required. Shipping prescription drugs and/or controlled substances direct to customers within a state requires licensure in most instances. The attached sheet identifies where Cardinal divisions are currently licensed and lists those states where out-of-state licensure is not required. This should assist you in identifying where to go for back-up.

RECORD KEEPING:

If you ship prescription drugs and/or controlled substances directly to another division's customer, your records (invoices, computer-generated sales history reports, ARCOS reports, etc.) must show that customer as the recipient of the product. The Prescription Drug Marketing Act (PDMA) and DEA regulations require wholesalers to maintain records of all transactions regarding the receipt and distribution of prescription and controlled drugs. These records must identify the "ship to" location.

We understand the importance of being able to provide this service to our customers. Our intention is not to restrict your ability to do so. Our purpose is to inform you of the regulatory requirements that must be met when doing so.

Joe Neary and I will work with our MIS groups to explore system support for the record keeping issues. In the interim, we are open to suggestions.

I hope this memorandum clearly identifies the issues at hand. If you have any questions or comments, please contact the Corporate Compliance Department at (614) 799-6050.



**U.S. Department of Justice
Drug Enforcement Administration**

Washington, D.C. 20537

SEP 14 1995

Ms. Diane Goyette
National Wholesale Druggists'
Association (NWDA)
Director of Regulatory Affairs
P.O. Box 2219
Reston, Virginia 22090-0219

Dear Ms. Goyette:

The Drug Enforcement Administration (DEA) is pleased to announce that the DEA Form 222 (U.S. Official Order Form - Schedule I and II) used to purchase controlled substances from DEA registrants has been changed for clarification purposes. The former line entitled "Number of Lines Completed" has been changed to "Last Line Completed".

This change was made as a result of requests made by DEA registrants to avoid confusion associated with the former requirement for an entry to be made for "number of lines completed". The new forms are already being distributed. Supplies of the old forms should continue to be used until they are depleted.

Please advise your membership of this change. We have enclosed a sample article which may be used for your publications. It is hoped that this change will obviate many problems associated with the former design of the form. If you have any further questions, please contact the Liaison and Policy Section at (202) 307-7297.

Sincerely,



G. Thomas Gitchel, Chief
Liaison and Policy Section
Office of Diversion Control

Enclosure

-6- 11 WSWL.WPS.

DEA CHANGES ORDER FORM (DEA-222)

The Drug Enforcement Administration (DEA) has announced that, at the request of registrants, a change has been made to the U.S. Official Order Form for Schedule I and II controlled substances (DEA-222). This change has been made for clarification purposes and involves the replacement of the line entitled "Number of Lines Completed" with "Last Line Completed".

The instructions pertaining to the change which appear on the reverse of each individual form indicate under item "8" the following: "Enter the last line completed - this generally should correspond to the number of lines used. If a number has not been entered, the form will be returned to you for completion before the supplier is allowed to fill it."

While DEA hopes that this clarification will eliminate much of the confusion the language of this part of the order form has caused some registrants over the years, they realize that errors will still occur due to misinterpretation. When it is clear to the supplier that the number of the last line completed has been incorrectly noted due to misinterpretation, rather than an attempt to facilitate diversion, the DEA form 222 should not be rejected.

The new clarified forms have already begun to be distributed although old forms should continue to be used until depleted.

Name of Registrant or Attorney-in-Fact		Name of Person to Whom Form is Being Submitted		DEA Approval No. 1117-072	
CITY and STATE		DATE		TO BE FILLED BY SUPPLIER	
TO BE FILLED BY SUPPLIER					
Line Number	Line Number	Line Number	Line Number	Line Number	Line Number
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
LAST LINE COMPLETED (MUST BE 10 OR LESS)		DEA REGISTRATION OR ATTORNEY-IN-FACT			
DEA Registration No.		Name and Address of Supplier			
Name and Address of Supplier		Name and Address of Supplier			
Name and Address of Supplier		Name and Address of Supplier			
U.S. OFFICIAL ORDER FORM - SCHEDULED I & II DEA ENFORCEMENT ADMINISTRATION SUPPLIES ONLY					
55690014					

See Reverse of PURCHASER'S Copy for Instructions		No order form may be issued for Schedule I and II substances unless a completed application form has been received. (21 CFR 1305.04).			OMB APPROVAL No. 1117-0010		
TO: (Name of Supplier) CARDINAL JAMES W. DALY, INC.			STREET ADDRESS 11 Centennial drive				
CITY and STATE Peabody, MA 01960		DATE 2/1/83		TO BE FILLED IN BY PURCHASER			
				SUPPLIERS DEA REGISTRATION NO.			
L I N E No.	TO BE FILLED IN BY PURCHASER						
	No. of Packages	Size of Package	Name of Item	National Drug Code		Packages Shipped	Date Shipped
	1	1	500 ml	Methadone 10 mg/5 ml Oral Sol.			
	2	6	100	MS Contin 60 mg Tablets			
	3	5	10	Morphine Sulf. Inj. 250 mg			
	4			Add-Vantage Vial 10 ml			
	5	1	100	Ritalin 5 mg tablets			
	6						
	7						
	8						
9							
10							
5 LAST LINE COMPLETED (MUST BE 10 OR LESS)			SIGNATURE OF PURCHASER OR ATTORNEY OR AGENT J. L. B.				
Date Issued 11-25-82		DEA Registration No. XXXXXXXXXX		Name and Address of Registrant Your Pharmacy 100 Main Street Anytown, USA 12345			
Schedules 2,2N,3,3N,4,5							
Registered as a Pharmacy		No. of this Order Form 987654321					
U.S. OFFICIAL ORDER FORMS - SCHEDULE I & II							
DEA Form -222 (Oct. 1982) DRUG ENFORCEMENT ADMINISTRATION SUPPLIER'S Copy 1							
46455319							

FOIA Confidential
Treatment Requested By
Cardinal

CONFIDENTIAL

CAH SWE 019364

CAH_MDL_PRIORPROD_DEA07_01384227



U.S. Department of Justice
Drug Enforcement Administration

Washington, D.C. 20537

[JUL 18 1996]

Ms. Diane Goyette
Director of Regulatory Affairs
National Wholesale Druggists Association
P.O. Box 2219
Reston, Virginia 22090-0219

Dear Ms. Goyette:

Thank you for your letter of April 29, 1996, voicing your organization's satisfaction with the April 17, 1996 semi-annual meeting with your membership. I know I speak for all Drug Enforcement Administration (DEA) personnel present at that meeting, in conveying their appreciation for the information presented and the cooperation received.

There are several issues that have been long-standing and we would like to bring you up to date with current activities. The proposed rule on freight forwarding has cleared DEA and is ready to be forwarded to the Department of Justice (DOJ) and the Office of Management and Budget (OMB) for their approval. The DEA ARCOS Unit has resolved the problem of "inadvertent under-reporting" that was attributed to differences in National Drug Code Numbers (NDC) pertaining to sizes. The ARCOS Unit has been able to take care of this problem internally without any further involvement of ARCOS participants.

The last issue centers around delivery of Schedule II order forms by drivers and the associated distribution scenarios. DEA has carefully reviewed the scenarios discussed at the April 17, 1996, meeting and has approved the following circumstances in which driver handling of Schedule II Order Forms (DEA Form 222) will be permitted, and the circumstances under which we will allow DEA Forms 222 to be transmitted by facsimile. DEA will permit the driver to handle DEA Forms 222 provided they are carried in a sealed envelope. DEA will permit the "faxing" of DEA Forms 222 by the customer to the DEA registered distribution center, in order to facilitate the expedient filling of the DEA Form 222. The distributor may prepare the order

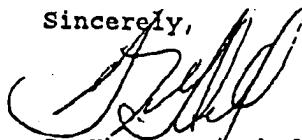
Ms. Diane Goyette

Page Two

from the facsimile and then compare the prepared order with the controlled substances, when the original DEA Form 222s arrive with the driver. Under no circumstances will DEA permit the driver to have the sole responsibility for reconciliation of the pre-prepared order with the actual DEA Form 222. DEA also does not approve of the scenario that allows the driver to "fax" the copy of the order form at the cross-docking facility. The cross-docking facility should only be used for the temporary storage of controlled substances in transit and DEA will not recognize any other activity, such as "faxing", at the facility. Further, the driver should have no knowledge as to the contents of the DEA Form 222. Also, it is the opinion of DEA that allowing the drivers to be responsible for sole reconciliation of Schedule II orders does not provide the "special handling" of Schedule II orders that the Controlled Substances Act mandates and the diversion possibilities presented by this scenario are obviously more plentiful.

Please convey this decision to your membership. We will inform all of our field offices of this approved procedure, in the hope that it will prevent admonishments such as the one that one of your members was given for allowing the driver to transport the DEA Forms 222. As always, it was a pleasure meeting with you and your membership. If you have any questions, please contact the Liaison and Policy Section at (202) 307-7297.

Sincerely,



G. Thomas Gitchel, Chief
Liaison and Policy Section
Office of Diversion Control

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U.S. Department of Justice
Drug Enforcement Administration

Washington, D.C. 20537

AUG 28 1996

Ms. Diane Goyette
Director of Regulatory Affairs
P.O. Box 2219
Reston, Virginia 22090-0219

Dear Ms. Goyette:

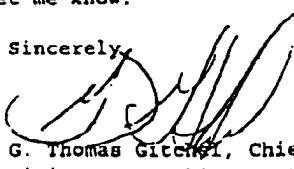
Reference is made to our recent meeting regarding the facsimile transmission of DEA forms 222 from retail pharmacies to distributors. As I advised you at that time, the Drug Enforcement Administration (DEA) will permit the facsimile transmission of an executed DEA form 222 directly from a retail pharmacy to a distributor to facilitate filling of an order, provided that the facsimile copy is compared with the original copy prior to shipping the order. It is acceptable, although in our view, not desirable, to permit a proprietary driver, acting as an agent/employee of the distributor, to "fax" a DEA form 222 on behalf of the pharmacy, to the distribution center. The practice of allowing common or contract carriers to "fax" DEA forms 222 to distribution centers, however, is not in the public interest and does not effectively guard against diversion.

We realize that distribution centers adopted procedures for facsimile transmission of DEA forms 222 to expedite delivery of controlled substances to their customers. Nevertheless, we are very concerned that a practice that enables common or contract truck drivers, who are subject to only limited security checks and controls, to know exactly what a particular shipment of drugs will contain, poses a significant threat of diversion.

We urge your members, therefore, to cease this practice as soon as possible. It has been represented that the practice of "faxing" DEA forms 222 by common and contract carriers is widespread and well-established in many of your members' distribution centers. Therefore DEA will recognize a transition period until December 31, 1996 to discontinue this practice.

If you have any questions, please let me know.

Sincerely,


G. Thomas Gitterman, Chief
Liaison and Policy Section
Office of Diversion Control



U. S. Department of Justice

Drug Enforcement Administration
Office of Diversion

Washington, D.C. 20537

Re: 17 1997

Diane P. Goyette, Director
Regulatory Affairs
National Wholesale Druggists' Association
P.O. Box 2219
Reston, Virginia 20195-0219

Dear Ms. Goyette:

This is in response to your letter of August 13, 1997, regarding the proper procedure for documenting liquid controlled substance loss through accidental breakage of its container.

1. You ask whether such loss should be reported using a DEA Form-41, "Registrants Inventory of Drugs Surrendered," or a DEA Form-106, "Report of Theft or Loss of Controlled Substances."

When a bottle containing a controlled substance is accidentally broken, the registrant should report the loss on a DEA Form-41. The DEA Form-41 is used to report the disposal of controlled substances in the registrant's possession. As you are aware, DEA requires that the loss be reported in order to account for all dispositions of the controlled substance within the closed distribution system. Any remaining controlled substance, with the container labeling, should be disposed of in accordance with Title 21, Code of Federal Regulations (21 CFR), Section 1307.21. A registrant should use a DEA Form-106 to report an unaccounted for loss, a theft or a loss in transit.

2. You also ask what a distributor should use in the "Associated Registrant Number" and "DEA Order Form Number" fields of the ARCCS report.

The DEA ARCCS Reporting Manual states that the registrant, in accounting for the loss on an ARCCS report, should place a code "Y" in the transaction field, and the DEA Area Office Registration Number in the "Associated Registrant Number" field. The "DEA Order Form Number" field should remain blank.

3. And lastly, you inquire whether DEA requires a distributor to keep the pieces of broken bottle as evidence of the incident.

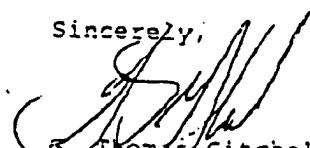
DEA does not require a registrant to keep the broken bottle pieces as evidence of the incident, but does require that the loss be documented as outlined above.

Diane P. Goyette

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I trust that the foregoing adequately answers your questions. If we may be of further assistance, please do not hesitate to contact this office at (202) 307-7297.

Sincerely,


G. Thomas Gitchel, Chief
Liaison and Policy Section
Office of Diversion Control

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